

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: DISCOVERY LABORATORIES : : MASTER FILE NO.
SECURITIES LITIGATION : : 06-1820
-----: :

MEMORANDUM

Dalzell, J.

March 15, 2007

_____ On November 1, 2006, we granted defendants' motion to dismiss in this case, finding that plaintiffs had not met the requirements of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). See In re Discovery Labs. Sec. Lit., 2006 WL 3227767 (E.D. Pa. Nov. 1, 2006) ("Discovery I"). We allowed plaintiffs an opportunity to amend their complaint and they have done so, responding to some (but by no means all) of the issues we raised in Discovery I. We now address defendants' renewed motion to dismiss for failure to meet the requirements of Rule 9 and the PSLRA. Because we reviewed the facts at length in our earlier opinion, see Discovery I at *1-*3, we will not do so here, but will in this sequel proceed straight to the legal analysis.

Plaintiffs allege that Discovery Labs and its executives made a series of false or misleading statements during the class period¹ in violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j, and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. The PSLRA requires that Rule 10b-5

¹ The class period runs from March 15, 2004 -- the date of the first allegedly fraudulent statement -- to June 6, 2006, the day Discovery withdrew its MAA from consideration with the EMEA.

plaintiffs must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). With regard to scienter, the PSLRA requires that "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Like all fraud cases, securities fraud complaints must also comply with the heightened pleading requirements of Fed. R. Civ. P. 9(b).²

A plaintiff may meet the scienter requirement either by showing "a motive and an opportunity to commit fraud, or by setting forth facts that constitute circumstantial evidence of either reckless or conscious behavior." Advanta, 180 F.3d at 534-35 (quoting Weiner v. Quaker Oats Co., 129 F.3d 310, 318 n.8 (3d Cir. 1997)). Whatever means plaintiff uses to address the scienter requirement, however, must be "stated 'with particularity' and must give rise to a 'strong inference' of scienter." Id. at 535 (quoting 15 U.S.C. § 78u-4(b)(2)).

² To the extent that the PSLRA and Rule 9 conflict, the PSLRA's more specific standard controls. In re Advanta Corp. Sec. Lit., 180 F.3d 525, 531 n.5 (3d Cir. 1999).

The Allegedly False or Misleading Statements

We have identified a total of thirty-five allegations in plaintiffs' complaint³ that particular statements are false or misleading in violation of Rule 10b-5. We have numbered them according to the complaint paragraph in which the allegation of falsity appears.

Three of the statements plaintiffs identify deal with claims regarding the shelf life of Surfaxin.⁴ In each of the statements, Discovery expressed the belief that Surfaxin might have a longer shelf life than the animal-derived surfactants currently on the market. Plaintiffs allege that this statement was false and misleading because Discovery had not conducted sufficient cGMP-compliant stability testing to support the claim. These statements cannot be the basis of a Rule 10b-5 claim for two reasons. First, these are clearly forward-looking statements under 15 U.S.C. § 78u-5(i)(1)(B).⁵ As such, they can only support liability if they are made with actual knowledge that they are false or misleading. 15 U.S.C. § 78u-5(c)(1)(B). Plaintiffs' allegation that Discovery had not done adequate testing to support this statement is, therefore, insufficient.

³ All references to the complaint are to the Second Consolidated Amended Complaint, dated November 30, 2006, unless otherwise specified.

⁴ These are statements 126a, 186b, and 229.

⁵ That subsection defines as forward-looking "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer."

Second, plaintiffs' allegations attempt to reverse the burden of proof for their claim. Discovery does not, as plaintiffs imply, have the burden to show that they had "conducted sufficient stability testing under current Good Manufacturing Practices to support" their claim. Compl. ¶ 126(a). Rather, the burden is on plaintiffs to show that defendants knew the statement was false or misleading. Because plaintiffs have failed to meet that burden, we will remove statements 126a, 186b, and 229 from our consideration.

Plaintiffs allege that seven of the statements about cGMP compliance at the Totowa facility made before Discovery received the FDA Form 483⁶ were false or misleading.⁷ Plaintiffs claim that these statements -- which substantially take the form "all steps required for production of cGMP material have been completed", e.g., Comp. ¶ 126(b) -- are false or misleading because, as it turns out, the Totowa production line was not cGMP compliant. Until Laureate gave them the Form 483, however, we cannot assume that Discovery knew that there were problems with cGMP compliance on the Surfaxin production line. As we noted in our earlier opinion, "plaintiffs must, at a minimum, allege the existence of some fact, known to defendants at the time of the statements, whose disclosure would have made the statement

⁶ Though it is not precisely clear when Discovery received the Form 483 from Laureate, it must have been some time between January 21, 2005 (when the report was issued) and February 1, 2005 (when Discovery issued its first press release on the subject).

⁷ The statements in this category are 126b, 126c, 126d, 128, 143, 156, and 164.

clearer or more correct." Discovery I, at *9 (emphasis added) (footnote omitted).

Plaintiffs claim that "[s]ince Discovery Labs received all of the batch records for all of Laureate's operations manufacturing Surfaxin® at Totowa, the defendants had timely notice of every deviation from cGMP that occurred during its operations manufacturing Surfaxin® at Totowa." Compl. ¶ 104. Even assuming that the batch records that Laureate provided to Discovery were accurate in every detail, this statement is clearly false. Most of the violations reported in the Form 483 had to do with documentation and investigation of problems. These would, of course, not be reported on the batch records because they are not related to the production of a batch. In addition, many of the non-documentation issues observed -- such as the shutdown of the air handling system between formulation and fill, see Compl., ex. 1, at ¶ 1(b) -- are not required to be reported on batch records, see 21 C.F.R. § 211.188. Plaintiffs' allegation that Discovery and its officers were aware of each of the violations prior to the Form 483 report, therefore, is patently false.

Furthermore, plaintiffs alleged in their first amended complaint that Discovery lacked adequate expertise in cGMP compliance, see Cons. Am. Compl. ¶¶ 121, 124, & 128. Now they claim (incredibly) that defendants had actual knowledge of "every deviation from cGMP that occurred during its operations" even before the FDA's inspection of the facility. Compl. ¶ 104. Because we find that plaintiffs have not adequately alleged that

defendants were aware of the cGMP violations at the Totowa facility prior to the FDA's Form 483, statements 126b, 126c, 126d, 128, 143, 156, and 164 are not actionable.

One would expect that a simple, factual, declarative sentence like "The FDA has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA," id. ¶ 154, could not, so long as it was not demonstrably false,⁸ form the basis of a securities fraud suit. Plaintiffs, however, think otherwise. They claim that, in order to avoid making the statement misleading, defendants were obliged to point out that completion by February 13, 2005 would depend on the FDA's determination that the manufacturing facility complied with cGMP.⁹ But the law does not require companies in regulated industries to append to every press release a tutorial on the applicable portion(s) of the Code of Federal Regulations. A reasonable investor in an early stage pharmaceutical company should be aware that the FDA may prevent a company from marketing a drug for a wide variety of regulatory failures.¹⁰ We find, therefore, that statement 154 is neither false nor misleading.

⁸ Plaintiffs do not claim that the FDA had not established a February 13, 2005 target date.

⁹ Plaintiffs also claim that defendants were aware on August 5, 2004 that the Totowa facility did not comply with cGMP. We have already found that plaintiffs' allegations are insufficient for us to impute that knowledge to the defendants.

¹⁰ Indeed, Title 21 of the C.F.R. occupies several volumes in the print edition. A great many of these regulations will, if not complied with, render a pharmaceutical product misbranded or adulterated and therefore unsaleable. 21 U.S.C. §331(a)-(c).

Plaintiffs also seek recovery for a number of statements¹¹ based on Discovery's failure to reveal that the actual clinical trials it conducted differed from those the EMEA¹² recommended. We discussed this issue at some length in our earlier opinion and concluded that these statements were not materially misleading. See Discovery I at *11-*13. Plaintiffs apparently hope that if they simply raise this issue again we will reach a different result this time.¹³ We republish our analysis in Discovery I and find that it applies equally well to

¹¹ The statements at issue here are 160, 190, 193, 200, 202, and 217.

¹² Faced with divergent guidance from the FDA and the EMEA, Discovery chose to follow the recommendations of the FDA. Plaintiffs have themselves noted that "[c]onducting clinical trials is time-consuming and expensive." Compl. ¶ 50. As we noted in our previous opinion "the company was involved in a complex negotiation with two different agencies to design a clinical program it could afford to complete that would lead to approval by both the FDA and the EMEA." Discovery I at *12. Plaintiffs' claim that Discovery's action "increased the risk that EMEA would deny approval," Pl. Mem. at 30, is correct, but it does not go far enough. Companies are not obliged to disclose every decision that improves the likelihood of one successful outcome (here the approval of the NDA) at the expense of another (here the MAA).

¹³ We have not tortured ourselves over the last five months about our decision of last November on this point. For the record, we stand by it.

the EMEA-related allegations in this complaint.¹⁴ Statements 160, 190, 193, 200, 202, and 217 simply add nothing to the mix.

We now reach the crux of plaintiffs' revised complaint: Discovery's February 1, 2005 announcement that it had received the Form 483 from the FDA and was not operating in compliance with cGMP. Plaintiffs first allegation regarding this announcement is that it "downplayed the seriousness of the FDA's observations."¹⁵ Compl. ¶ 174. We note, however, that in response to the announcement Discovery's stock price dropped more than 22%. Compl. ¶ 176. Thus, even if it was defendants' intention to downplay the significance of the Form 483, they were dramatically unsuccessful in doing so. The market unambiguously regarded this announcement as most significant. While defendants may have attempted to put a positive spin on what was clearly a very bad development for Discovery, that is not, by itself, enough to form the basis for liability. "Rule 10b-5 liability

¹⁴ Plaintiffs have added an argument that the EMEA statements are actionable under a recklessness theory. Pl. Mem. at 49. They apparently misunderstand, despite the discussion in our earlier opinion, see Discovery I, at *14-*15, how recklessness is used in this sense. Plaintiffs appear to claim that defendants were reckless for ignoring the EMEA's guidance. Even if that is true, it is irrelevant. Recklessness is used in the securities fraud context as a substitute for scienter. No one disputes that Discovery and its officers knew they were deviating from the EMEA's guidance. Because everyone agrees that defendants had actual knowledge, plaintiffs accomplish nothing by pleading recklessness as well.

¹⁵ Plaintiffs apparently believe that, because the Form 483 had expressed concern that there was "no assurance" that Surfaxin could be manufactured to the required standards, see Pl. Mem. at 37, Discovery was required to refrain from opining that the problems at Laureate could be solved. Corporate officers do not need "assurance" in order to make positive statements about the future. They need only avoid actual or constructive fraud.

does not attach merely because '[a]t one time the firm bathes itself in a favorable light' but '[l]ater the firm discloses that things are less rosy.'" Advanta, 180 F.3d at 538 (quoting DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990)). It is not the role of the courts to split hairs over how positively corporate executives are allowed to describe a negative event. It is sufficient that the markets were aware that the Form 483 was a serious setback for Discovery. Statement 174, therefore, cannot form a basis for liability.

Plaintiffs' next allegation represents a fundamental misunderstanding of what the Form 483 found. Here and elsewhere in the complaint, plaintiffs make much of the statement in the Form 483 that there was "no technical transfer of the manufacturing process." Compl., ex. 1, ¶ 1. While plaintiffs would perhaps like this to mean that Discovery provided Laureate no guidance whatsoever on how to manufacture Surfaxin, that would be absurd.¹⁶ Instead, the only reasonable interpretation of this finding is that whatever technology transfer occurred was improperly documented.

In that light, nothing about the Form 483 makes Discovery's earlier statement -- that the FDA's "pre-approval inspections of Discovery's clinical data and clinical study sites have been extremely favorable" -- in any way misleading. Compl.

¹⁶ As plaintiffs noted in their previous complaint, "[t]he manufacturing process to produce Surfaxin is complex and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients." Cons. Am. Compl. ¶ 173 (quoting May 4, 2006 Form S-3 at 2). Setting the Totowa facility up to produce the drug at all required significant technical transfer.

¶ 175. The important implication of Discovery's statement is that no additional clinical trials would be required for FDA approval. That appears still to be the case. Indeed, the FDA issued an approvable letter for Surfaxin just three weeks after the Form 483, something it would not have done had there been concern about the clinical trials that supported the Surfaxin NDA. While the Form 483 identified significant manufacturing issues that would need to be addressed, it did not implicate any of the clinical data that had been submitted as part of the NDA. Statement 175, therefore, is not materially misleading.

Statement 178 deals with the conference call, also held on February 1, 2005, that addressed the Form 483. Plaintiffs make several allegations in regard to that call. As to their claim that the call as a whole downplayed the seriousness of the report, our analysis of the identical claim about the press release in statement 174 holds here as well: given that the stock dropped more than 20% as a result of the announcement, no reasonable finder of fact could say that the statement was materially misleading because it did not cause a greater drop.

Plaintiffs next take issue with the statements "these are not issues related to the manufacturing process itself" and "these observations in the 483 do not implicate any fundamental flaws in the actual Surfaxin production process itself, the manufacturing equipment or the integrity of Surfaxin used in our clinical trials." Compl. ¶ 178. Taken in context, however, these statements are factually accurate. The Form 483 dealt primarily with failure properly to control conditions, failure to

investigate variations from those controls, and failure to keep proper documentation. These are not issues with the manufacturing process itself that would require a redesign of the process, and which would, in turn, cast doubt on the validity of the clinical trials. Rather, the issues raised are the sorts of problems that, while they may be expensive or time-consuming to remedy, are eminently correctable. Indeed, if the FDA had not believed that Discovery could remedy the problems in short order without casting doubt on the clinical trials, it would not have issued an approvable letter three weeks later.

The fact that, more than two years later Discovery has not been able to remedy the problems, also does not make the earlier statements false or misleading. The mere fact that defendants' statements turned out to be overly optimistic does not make them fraudulent. This is what Judge Friendly memorably referred to as "fraud by hindsight." Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978).¹⁷ In order to make out a securities

¹⁷ Judge Easterbrook's description for the Seventh Circuit of fraud by hindsight could just as easily apply to this case:

The story in this complaint is familiar in securities litigation. At one time the firm bathes itself in a favorable light. Later the firm discloses that things are less rosy. The plaintiff contends that the difference must be attributable to fraud. "Must be" is the critical phrase, for the complaint offers no information other than the differences between the two statements of the firm's condition. Because only a fraction of financial deteriorations reflects fraud, plaintiffs may not proffer the different financial statements and rest. Investors must point to some facts suggesting that the

(continued...)

fraud claim, plaintiffs must allege that defendants knew they were being overly optimistic. This plaintiffs have not done. Plaintiffs have not alleged that defendants had any knowledge of the problems at Laureate beyond what was documented in the Form 483. We cannot hold defendants liable because they read that report in much the same way as the FDA did and remained optimistic that the problems could be timely resolved. Statement 178 is, therefore, not materially false or misleading.

The last statement at issue from February 1, 2005 is Robert Capetola's that "[t]he level of scrutiny for our commercial process is much higher than needed in our clinical supply." Compl. ¶ 179. This is an obvious misstatement of the relevant federal regulations. See 21 C.F.R. § 211.1(a) (establishing a single set of manufacturing standards for both clinical and production batches). We cannot see, however, how this statement "would have been viewed by the reasonable investor as having 'significantly altered the "total mix" of information' available to that investor." In re Westinghouse Sec. Lit., 90 F.3d 696, 714 (3d Cir. 1996) (quoting TSC Indus. v. Northway, Inc., 426 U.S. 438, 449 (1976)). Once the Form 483 had been issued, it made no difference to a reasonable investor whether the problems were the result of increased scrutiny or not. What

¹⁷ (...continued)
 difference is attributable to fraud. That ingredient is missing in [plaintiffs'] complaint.... There is no "fraud by hindsight", in Judge Friendly's felicitous phrase and hindsight is all [plaintiffs] offer.

DiLeo, 901 F.2d at 627-28 (internal citations omitted).

mattered was that, in order to get Surfaxin to market, Discovery was going to have to fix the problems. Statement 179, therefore, is not material.

Over the next fourteen months, defendants made a number of additional statements consistent with their initial analysis of the Form 483. We have already found that the initial analysis was not misleading for the reasons discussed in the preceding pages. Plaintiffs do not allege that these consistent statements are false or misleading because of additional information that defendants learned of, but rather because defendants continued to downplay the significance of the Form 483. Because we have already found that defendants' initial statements were not materially misleading, we must make a similar finding about these subsequent statements. Statements 184, 188, 192, 195, 198, 204, 209, 219, and 235 do not advance plaintiffs' cause.

In paragraph 186(a), plaintiffs claim that the statement "'[w]e believe that our precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants' was false and misleading because the defendants had not yet established a facility that was capable of producing Surfaxin® consistent with current Good Manufacturing Practices." Compl. ¶ 186(a). This averment fails for two reasons. First, it reverses the proper burden of proof in a securities fraud case. Plaintiffs' claim would require that defendants not make such a statement of belief until they had "established a facility that was capable of producing Surfaxin®"

under cGMP. This would place the burden on Discovery and its officers to show that their statement was true, a clear reversal of the actual legal burden under Rule 10b-5.¹⁸ Second, this statement is a forward-looking statement as defined in 15 U.S.C. § 78u-5(i)(1)(B). Thus, in order to use this statement as the basis for a securities fraud claim, plaintiffs must allege that it was made with actual knowledge of its falsehood and that it was not accompanied by meaningful cautionary language. 15 U.S.C. 78u-5(c)(1). This statement was made as part of Discovery's 2004 10-K report, filed with the SEC and reproduced as exhibit 41 in support of defendants' original motion to dismiss. In that report, after discussing the Form 483 that had been issued, Discovery warned that "[i]f the FDA does not accept the cGMP Action Plan, or we or Laureate do not adequately address the initiatives set forth therein, the FDA may delay its approval of our NDA for Surfaxin or reject our NDA." Def. Mem., ex. 41, at 42. Even with the benefit of hindsight, we are unable to dream up any more meaningful cautionary statement that Discovery could have included in the report. This is obviously the sort of statement that 15 U.S.C. § 78u-5 is meant to protect.

Paragraph 186c attacks defendants' statement, again in the 2004 10-K, that Surfaxin might have a longer shelf life than animal derived surfactants. The animal-derived surfactants typically have a shelf life of between twelve and twenty-four

¹⁸ The plaintiffs' standard would, in fact, prevent companies from ever making statements of belief and would hold them liable whenever their beliefs turned out to be incorrect. This is palpably not the intent of the federal securities laws.

months. Compl. ¶ 186(c). Plaintiffs claim that, in light of a statement made on April 25, 2006 that Discovery was "shooting for" a shelf life of between twelve and twenty-four months "out of the gate," the earlier statement was false. Id. This is, of course, merely another allegation of fraud by hindsight.

Plaintiffs cannot use a statement made in April of 2006 to prove the falsehood of a statement made in March, 2005. Because there are no allegations that Discovery had already decided to "shoot for" a twelve to twenty-four month shelf life in March of 2005, this statement will not support plaintiffs' claim.

In both the August 5, 2005 and November 9, 2005 10-Qs, Discovery said that "[w]e believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support this response prepare us for the FDA's reinspection of Laureate's Totowa facility." Compl. ¶¶ 205, 221. These are forward-looking statements, and both of those reports contained cautionary language largely identical to that quoted above in the discussion of statement 186a. Further, in order to use them in support of a securities fraud claim, plaintiffs would have to allege actual knowledge that the statements were false. In other words, they would need to allege that Discovery and its officers did not actually believe that the FDA inspection would be successful. In addition, they would need to "state with particularity facts giving rise to a strong inference" that defendants did not actually hold that belief. 15 U.S.C. § 78u-4(b)(2). Instead, they merely allege that proper manufacturing methods had not been put in place.

Even if we were to interpret plaintiffs' complaint as alleging defendants' actual knowledge that the Totowa facility would fail its reinspection, we would still not allow plaintiffs to proceed. "[A] pleading of scienter 'may not rest on a bare inference that a defendant 'must have had' knowledge of the facts.'" Advanta, 180 F.3d at 539 (quoting Greenstone v. Cambex Corp., 975 F.2d 22,26 (1st Cir. 1992) (Breyer, J.)). Because, at best, such an inference is all plaintiffs provide, their claim cannot stand.

A similar problem applies to the final statement, number 231. In its 2005 10-K, Discovery said "[a]ssuming that the corrective actions made to the Surfaxin manufacturing operations in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006." Compl. ¶ 231. Plaintiffs allege that, because Discovery had not properly completed its remediation, this statement was materially false and misleading. There can be no doubt that it is a forward-looking statement. Here, as before, plaintiffs lack the kind of allegations about actual knowledge of the statement's falsehood that would be required to survive the present motion to dismiss.

Defendants' Stock Sales

Because we have eliminated several of the statements above on scienter grounds, we must address plaintiffs' alternative claim that they can establish scienter by "establishing a motive and an opportunity to commit fraud." Weiner, 129 F.3d at 318 n.8. Plaintiffs make this claim on the

basis of Capetola's and Schaber's sales of common stock.¹⁹ Sale of stock is a valid basis for inferring scienter, but "plaintiffs must allege that the trades were made at times and in quantities that were suspicious enough to support the necessary strong inference of scienter." In re Burlington Coat Fact. Sec. Lit., 114 F.3d 1410, 1424 (3d Cir. 1997).

Plaintiffs' only allegation with regard to the timing of the sales is that the first of them came two weeks after the investigation of the November 7, 2003 manufacturing overrun. Capetola's second sale came three weeks later, and Schaber's sale came another three weeks after that. The sales were not suspiciously large, representing between a half and two-thirds of Capetola's total holdings and less than a third of Schaber's. This is inadequate to "support the necessary strong inference of scienter." Id. (emphasis added).

Because we find that plaintiffs have not met the required pleading standards for any of the fraudulent statements they allege, we will grant defendants' motion to dismiss.

Section 20(a) Claim

Plaintiffs assert a claim under Section 20(a) of the Exchange Act. As it is derivative of their Rule 10b-5 claim, it, too, must be dismissed.

¹⁹ In our previous opinion, we reached the conclusion that "there is no real difference between the [Variable Prepaid Forward Contracts] here and any other sale of stock." Discovery I, at *14. Plaintiffs seem to concur, see Compl. ¶ 116, so we will analyze the transactions as if they were ordinary stock sales.

BY THE COURT:

/s/ Stewart Dalzell, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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ORDER

AND NOW, this 15th day of March, 2007, upon consideration of defendants' motion to dismiss (docket entry # 52), plaintiffs' response (docket entry # 56), and defendants' reply (docket entry # 60) and for the reasons articulated in the accompanying Memorandum of Law, it is hereby ORDERED that:

1. Defendants' motion to dismiss is GRANTED;
2. Plaintiffs' second consolidated amended complaint is DISMISSED; and
3. The Clerk of Court shall CLOSE this matter statistically.

BY THE COURT:

/s/ Stewart Dalzell, J.